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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
WOODWARD, CHERIE MICHELLE	

ART UNIT	PAPER NUMBER
1647	

MAIL DATE	DELIVERY MODE
10/27/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/525,363	LAWLOR ET AL.	
	Examiner	Art Unit	
	CHERIE M. WOODWARD	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,8,12,13,22,29-32 and 36* is/are pending in the application.

4a) Of the above claim(s) *22,29-32 and 36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,8,12,13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/18/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Formal Matters

1. Applicant's Response and amendments to the claims and the specification, filed 7/8/2008, are acknowledged and entered. Claims 6-7, 9-11, 14-21, 23-28, 33-35, and 37-45 have been cancelled by Applicant. Claims 22, 29-32, and 36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claims 1-5, 8, 12, and 13 are under examination.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 4/18/2008 has been fully considered. A signed copy is attached.

Response to Arguments

Objections/Rejections Withdrawn

3. The objection to the title is withdrawn in light of Applicant's amendment.

4. The objection to claim 13 related to now cancelled claim 11 and its recitation of the term "antagonist" is withdrawn as moot in light of Applicant's cancellation of claim 11.

5. The rejections over claims 11, 14, and 18 are withdrawn as moot in light of the cancellation of these claims.

6. The rejection of claims 1 and 18 under 35 U.S.C. 112, first paragraph, scope of enablement is withdrawn in light of Applicant's amendments.

7. The rejection of claims 1-3, 5, and 8 under 35 U.S.C. 102(b) as being anticipated by Hamilton et al., US Patent 5,449,515 (12 September 1995), is withdrawn in light of Applicant's amendments.

Objections/Rejections Maintained

8. The objection to the disclosure is maintained because the last paragraph of page 32 is difficult to read. Applicant was requested to provide a readable copy of the last paragraph of page 32. Applicant

reproduced the paragraph in the Remarks, but a substitute paragraph in the nature of an amendment to the specification is requested clearly showing the text of the paragraph in question.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 1-5, 8, 12, and 13 remain rejected under 35 U.S.C. 102(e) as being anticipated by Devalaraja et al., US Patent Application Publication 20070059280 (published 15 March 2007, benefit to 20 March 2000), as evidenced by Luross et al., (Immunology. 2001 Aug;103(4):407-16, Abstract only), for the reasons of record and the reasons set forth herein.

Applicant argues that the '280 publication does not adequately anticipate the claims (Remarks, p. 9, second paragraph). Applicant argues that the therapeutic methods taught by the '280 publication are based on an observation of the synergistic effect of exogenously added G-CSF on cytokine-mediated inflammation (Remarks, p. 9, second paragraph). Applicant argues that the '280 publication does not provide any evidence with respect to the rule of endogenously produced G-CSF in inflammation and that the teachings of the '280 publication do not adequately support a method of treating a disease based on inhibiting endogenous G-CSF (Remarks, p. 9, second paragraph). Applicant also argues that the present application provides evidence for a role of endogenously produced G-CSF in promoting inflammation in vivo using G-CSF gene knockout mice (Remarks, p. 9, last paragraph to p. 10, first paragraph). Applicant argues that the '280 publication does not provide a showing based on an accepted experimental model of arthritis (Remarks, p. 10, second paragraph). Applicant also argues that the '280 publication is not adequately enabled (Remarks p. 10, last paragraph). Applicant's arguments have been fully considered, but they are not persuasive.

With regard to Applicant's arguments directed to a lack of enablement and evidence with respect to endogenously provided G-CSF, the '280 publication specifically states that evidence of the involvement of G-CSF and G-CSFR in inflammation *in vivo* is well known in the art (see background

section, paragraph 3, discussing known models of transgenic and knockout G-CSFR mice; and paragraph 21). The '280 publication need not teach what is old and well known in the art in order to be enabled. The fact that the '280 publication does discuss what is well known in the art is sufficient for the disclosure of the '280 publication to meet the requirements of 35 USC 112, first paragraph.

With regard to Applicant's argument directed to the synergistic effect of exogenously added G-CSF, Applicant focuses its argument on only one alternative embodiment of the '280 publication. Applicant's attention is drawn to paragraphs 33-43 where the method of *in vivo* treatment is directed to treatment of inflammation caused by endogenous mediators. Treatment of rheumatoid arthritis is specifically discussed in paragraph 42 and "especially preferred inhibitors" are monoclonal antibodies to G-CSF or G-CSFR (paragraph 32).

With regard to Applicant's arguments that the '280 publication does not provide a showing based on an accepted experimental model of arthritis, such a showing is not required where the '280 publication teaches treatment of rheumatoid arthritis by administering antibodies against G-CSF or G-CSFR and the art teaches that collagen-induced arthritis is an accepted animal model of rheumatoid arthritis, as evidenced by the Luross et al., publication, cited of record. Moreover, as stated above, the '280 publication teaches known models of transgenic and knockout G-CSFR mice (paragraph 3).

The '280 publication teaches a method of treating inflammation or an autoimmune disease comprising administering to a mammal in need thereof a therapeutically effective amount of an inhibitor of a G-CSF which inhibits inflammation or autoimmune disease (paragraph 36; claims 12 and 16) (compare instant claims 1, 2, and 5). Treatment of rheumatoid arthritis is taught at paragraph 42 and claim 18 (compare instant claim 3). Inhibitors of G-CSF and G-CSFR which inhibit activation or antagonists of G-CSF and G-CSFR, including antibodies (paragraph 31) and monoclonal antibodies (paragraphs 32 and 88) (compare instant claims 1, 12, and 13). Administration of anti-G-CSF antibodies to a human are taught at paragraph 106 (compare instant claim 8). Administration of soluble G-CSFRs which prevent interaction with naturally-occurring receptors is taught at paragraphs 107 and 111 (compare instant claim 1). The '280 publication defines autoimmune diseases to include those with anti-collagen antibodies, thereby encompassing collagen-induced arthritis (paragraph 101) (compare instant claim 4). It is also old and well-known in the art that collagen-induced arthritis is an animal model of human rheumatoid arthritis (see, for exemplary purposes only, Luross et al., abstract) (stating "[c]ollagen-induced arthritis has also been the model of choice in terms of testing potential new therapeutic agents for the treatment of human RA.") (compare instant claim 4).

New Claim Rejections – Necessitated by Amendment

Provisional Obviousness-Type Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1, 5, and 8 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13 and 14 of copending Application No. 10/559,771 in view of Devalaraja et al., US Patent Application Publication 20070059280 (published 15 March 2007, benefit to 20 March 2000). Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the reference claims embraces the method of the instant claims. The reference claims are drawn to a method of modulating G-CSF-induced cellular responses in a mammal comprising administering an effective amount of an isolated compound which modulates G-CSF-induced cellular responses in a human. The specification of 10/559,771 discloses that the modification of G-CSF-induced cellular responses includes down-regulating or inhibiting G-CSF signaling (page 6, lines 11-12; p. 11, lines 5-8). Downregulation of G-CSF is taught in reducing unwanted clinical sequelae of inflammatory processes including arthritis (p. 36, lines 16-16 and 19).

Although neither the claims nor the specification of the '771 publication specifically disclose G-CSF or G-CSFR antibodies, the prior art '280 publication teaches a method of treating inflammation or an autoimmune disease comprising administering to a mammal in need thereof a therapeutically effective amount of an inhibitor of a G-CSF which inhibits inflammation or autoimmune disease (paragraph 36; claims 12 and 16) where the inhibitors of G-CSF and G-CSFR which inhibit activation of G-CSF and G-CSFR include antibodies (paragraph 31) and monoclonal antibodies (paragraphs 32 and 88). Administration of anti-G-CSF antibodies to a human are taught at paragraph 106. As such, the reference claims fully embrace the instantly claimed invention and therefore, a person of ordinary skill in the art would conclude that the invention defined in instant claims 1, 5, and 8 would have been an obvious variation of the invention defined in claims 13 and 14 of the '771 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

NO CLAIM IS ALLOWED.

13. The prior art made of record, but not presently relied upon is considered pertinent to applicant's disclosure.

a. Devalaraja et al., US Patent 7,108,852 (19 Sept 2006, benefit to 23 Feb 2001) teaches methods of treating inflammation using antibodies to M-CSF, G-CSF, and G-CSFR. The '852 patent is the parent of the '280 application, cited of record (see above).

b. Nicholson et al., US Patent 5,902,584 (11 May 1999) teaches antibodies which bind G-CSR and methods of treatment.

c. Smith et al., WO 91/05046 (18 Apr 1991) (cited in Applicant's IDS of 4/18/2008) teach G-CSFRs and methods of treatment.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH

shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERIE M. WOODWARD whose telephone number is (571)272-3329. The examiner can normally be reached on Monday - Friday 9:00am-5:30pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CMW/

AU 1647

/Gary B. Nickol /

Supervisory Patent Examiner, Art Unit 1646